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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,577	04/02/2004	Shilpa S. Thosar	3168/7/US	3792

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,577	THOSAR ET AL.	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-72 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-72 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-72 are pending prosecution.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,534,093; claims 1-65 of U.S. Patent No. 6,410,054; claims 1-10 of U.S. Patent No. 6,592,902; claims 1-62 of U.S. Patent No. 6,558,707 and claims 1-21 of U.S. Patent No. 6,495,165. Although the conflicting claims are not identical, they are not patentably distinct from each of the above sets of patented claims. The above patents also claim pharmaceutical compositions containing micronized eplerenone having a specific particle size and pharmaceutical excipients, so as to achieve a specific dissolution pattern. The patented claims also recite the pharmaceutical excipients and method of use, as claimed in the instant application. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare micronized eplerenone compositions comprising various pharmaceutical excipients in different amounts and an

appropriate particle size of eplerenone because each of the above patents also claim compositions comprising the same components and for the same purpose i.e., block aldosterone receptor.

Claims 1-73 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of copending Application No. 10/2879,025 and claims 11-13 of copending Application No. 10/417,602. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant claims and the copending claims recite pharmaceutical compositions containing micronized eplerenone in an amount of 10-1000 mg. Further, the copending claims and instant claims a method of treatment so as to achieve the same purpose by administering the instant composition. Accordingly, one of an ordinary skill in the art would have been motivated to use the composition of the copending claims, and still achieve the claimed effect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 66 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Instant claim recites the use of micronized eplerenone and a cellulosic carrier, without actually reciting the steps involved in the use.

Claim 66 is provides for the use of micronized eplerenone and a cellulosic carrier, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 66 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grob et al (US 4,559,332) in view of Bernini (US 4,332,721) and Fincher (J. Pharmaceutical Sciences).

Grob teaches spiroxanes and analogues of spiroxanes for the treatment of hyperaldosteronism and the diseases associated with the same (applicants admit the same in page 1 of the specification). Grob teaches administering the composition for upto 2 daily dosage units (col. 15, lines 25-35). Further, Grob teaches oral tablet preparation or capsule preparations that incorporate the claimed diluents, disintegrants, wetting agents etc (col. 28) such as sorbitol, magnesium stearate, celluloses, talc, starch, gelatin etc. Further, the process of preparing the composition of Grob (col. 28) meets the requirement of instant claims. Grob teaches micronized preparations (col. 28), however fails to teach micronized eplerenone.

Bernini teaches spironolactone composition and the process of preparing micronized spironolactone with increased biological activity. Bernini teaches spironolactone particles between the sizes of 2 to 5 microns (col. 1). While spironolactone is different from the claimed eplerenone, the former also belongs to the class of epoxy compounds and also possess anti-aldosterone activity.

Fincher teaches that the larger particles of drug give local activity in GI tract ad smaller particles are required for absorption through the gut. Fincher teaches that the drug absorption and release rates can be determined using in vitro measurement (page 1826, col. 2). Further, Fincher teaches that the absorption of the drug from particles appears to increase with an increase in the specific surface area and that an improved dissolution rate leads to greater bioavailability (page 1827). Fincher teaches several drugs including micronized spironolactone capsules (table 1 on page 1829). Further, the effect of particle size on release of drugs from dosage forms in vitro and drug absorption.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the invention to prepare micronized forms of eplerenone (of Grob), in an appropriate particle size, because Bernini teaches micronization of spironolactone for increased biological activity and Fincher also suggests preparing particulate forms of drugs such as spironolactone for increased biological activity because particle size increases the surface and thus increases the area of drug absorption. Accordingly, optimizing the particle size of eplerenone in a suitable range with an expectation to achieve a formulation having a desired release rate is within the scope of a skilled artisan. With respect to the claimed release rate, Fincher suggests measuring the drug absorption using in vitro measurement rates.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615
September 29, 2004